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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/289,000 02/25/97 BLATT

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EXAMINER

QM12/0712

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PREPUBLICATION

ART UNIT

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3738

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/289,000

Applicant(s)
Blatt

Examiner
Paul Prebilio

Art Unit
3738



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 4, 2001
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8-10, and 24-31 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-10, and 24-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

Art Unit: 3738

Claim Rejections Based Upon Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-6, 8-10, and 24-31 are rejected under 35 U.S.C. 102(b) as anticipated by Cohen (US 5,207,712) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cohen (US 5,207,712) alone. Cohen (US 5,207,712) anticipates the claim language wherein the resection of bone ends or the holes drilled into the bone ends expose the cancellous bone surface and the solid sphere and rods allow both for the joint to flex and extend after implantation (see Col. 4, lines 38 and 39) and the ball (4) provides a sliding surface for the joint ends; see the whole document, especially Col. 3, lines 18-20; Col. 4, lines 3-39 and Figures 1-3 and 8-11.

Alternatively, one could view the ball (4) as not providing a sliding surface because it is not explicitly stated as providing such. However, the Examiner posits that one viewing this embodiment would be led to the conclusion that the ball (4) obviously functions as a stop and

Art Unit: 3738

sliding surface for the resected bone ends because the joint flexes and extends around the ball surface; see column 4, lines 38-39.

With regard to claims 8 and 9, Applicant is directed to Figure 1 and especially Figure 2 for claim 8. It is noted that the first and second face of Cohen is on opposed sides of the spacer such that it reads on the claim language.

With regard to claim 24 specifically, the Examiner posits that a period of 6 to 7 months would be sufficient to allow all the natural processes of the permitting step as claimed to take place; see Col. 2, lines 45-48.

With regard to claims 4, 10, and 25 specifically, the estimating step as claimed is inherently or implicitly present in Cohen who makes his device for a particular joint type so that as much regrowth between the joints can take place.

Claims 2 and 3 are rejected under 35 U.S.C. § 103 as being unpatentable over Cohen (US 5,207,712) in view of Delcommune et al (US 5,007,939). Cohen meets the claim language except for the use of lactic acid polymer or copolymer as claimed. Delcommune et al, however, teaches that it has been known to use lactic acid polymer or copolymer for resorbable bone repair devices. Hence, it is the Examiner's position that it would have been obvious to one of ordinary skill in the art to use lactic acid polymer or copolymer in place of in addition to the polymer of Cohen for the same reasons that Delcommune et al uses the same and in order to further reduce the cost of making the device.

Art Unit: 3738

Response to Arguments

Applicant's arguments filed May 4, 2001 have been fully considered but are not persuasive with respect to the prior art rejections.

In response to the traversal of the 35 USC 112 rejections of the previous response filed January 8, 2001, the Examiner reviewed Applicant's arguments as they pertain to the rejection and found that there was implicit support for this in the specification on page 7, lines 8-13. However, the Examiner posits that such essential subject matter should have explicit support from the disclosure. For this reason, the Examiner again respectfully requests amending the specification to give explicit antecedent support to this claimed subject matter so that the claimed subject matter has antecedent basis from the disclosure.

In response to the Applicant's argument that there is "no possibility" that opposing resected surfaces slide with respect to each other, the Examiner notes that this argument is not commensurate with the claims' scopes which do not require slidable motion between the resected ends. Furthermore, the disclosed invention does not provide such a structure because the implant provides at least one of the sliding surfaces.

With regard to the argument that sliding motion is prevented by Cohen, the Examiner respectfully disagrees and takes the position that since the joint can flex and extend with the implant in place (see Col. 4, lines 38-39) that sliding on the ball (4) face would occur. Furthermore, only claims 27-31 require lateral sliding motion between the joint and the implant face as Applicant's argues. Since the implant surfaces of Cohen provide sliding surfaces in the

Art Unit: 3738

flexion and extension direction, lateral or side-to-side motion would also be provided when the spacer was a ball. Furthermore, even with the Figure 2 embodiment, some lateral sliding would take place inherently because it could not be prevented absolutely. For these reasons, the claim language is considered fully met in this regard.

Next, Applicant argues that no slidable joint movement is possible with the Cohen devices. However, the Examiner respectfully disagrees and maintains that column 4, lines 38-39 explicitly states that the joint can flex after implantation of the implant. The Examiner cannot interpret the language different than what it explicitly states. For this reason, a slidable movement over the spacer is clearly provided.

Applicant also argues that the rods of Cohen are solid suggesting that they are rigid also. However, Cohen states that the joint can flex and extend once the implant is located in the joint, and thus, the rods cannot be rigid throughout, otherwise it would not function as stated. The Examiner cannot interpret the language contrary to what it explicitly states.

In response to the assertion that joint fusion is a goal of Cohen, the Examiner respectfully disagrees and takes the position that the opposite is true. Column 2, lines 37-44 explains that the gap of 1 mm or more is to prevent "growth of bone" (i.e. bone fusion) between the bone ends. The Examiner asserts that this gap leads to an articulating joint.

The declaration under 37 CFR 1.132 filed May 4, 2001 is insufficient to overcome the rejection of claims 1-6, 8-10, and 24-31 based upon Cohen as set forth in the last Office action because:

Art Unit: 3738

(1) It refer(s) only to the system described in the above referenced application and not to the individual claims of the application. Thus, there is no showing that the opinion evidence of nonobviousness is commensurate in scope with the claims. See MPEP § 716.

(2) The declarant has a vested interest in the application in that he is the applicant thereof.

(3) Arguments or opinion evidence, although considered as provided does not make the ultimate legal conclusion of patentability; see MPEP 716.01(c) which is incorporated herein by reference thereto.

(4) In particular, in response to the Applicant's argument that there is "no possibility" that opposing resected surfaces slide with respect to each other, the Examiner notes that this argument is not commensurate with the claims scopes which do not require slidable motion between the resected ends. Furthermore, the disclosed invention does not provide such a structure because the implant provides at least one of the sliding surfaces.

(5) With regard to the argument that sliding motion is prevented by Cohen, the Examiner respectfully disagrees and takes the position that since the joint can flex and extend with the implant in place (see Col. 4, lines 38-39) such that sliding on the ball (4) face would inherently occur. Furthermore, only claims 27-31 require lateral sliding motion between the joint and the implant face as Applicant's argues. Since the implant surfaces of Cohen provide sliding surfaces in the flexion and extension direction, lateral or side-to-side motion would also be provided when the spacer was a ball. Furthermore, even with the Figure 2 embodiment, some lateral sliding

Art Unit: 3738

would take place inherently because it could not be prevented absolutely. For these reasons, the claim language is fully met in this regard.

(6) Next, Applicant argues that no slidable joint movement is possible with the Cohen devices. However, the Examiner respectfully disagrees and maintains that column 4, lines 38-39 explicitly states that the joint can flex after implantation of the implant. The Examiner cannot interpret the language different than what it explicitly states. For this reason, a slidable movement over the spacer is clearly provided.

(7) Applicant also argues that the rods of Cohen are solid suggesting that they are rigid also. However, Cohen states that the joint can flex and extend once the implant is located in the joint, and thus, the rods cannot be rigid. The Examiner cannot interpret the language contrary to what it explicitly states.

(8) In response to the assertion that joint fusion is a goal of Cohen, the Examiner respectfully disagrees and takes the position that the opposite is true. Column 2, lines 37-44 explains that the gap of 1 mm or more is to prevent "growth of bone" (i.e. bone fusion) between the bone ends. The Examiner asserts that this gap leads to an articulating joint.

(9) Applicant also argues that Cohen provides for a rigid connection between the bone ends. However, the Examiner asserts that there is no evidence, either objective or from the Cohen patent, of this conclusion can be found. For this reason, it is not considered persuasive in view of the fact that Cohen states that flexion and extension of the joint occurs after implantation; column 4, lines 38-39.

Art Unit: 3738

(10) Next, Applicant alleges that damage or breakage would occur to the rods of Cohen. In response, the Examiner posits that there is no evidence of this in Cohen or in the record. The Examiner suggests the Applicant provide objective evidence of this alleged characteristic.

(11) Finally, Applicant argues that Cohen, on column 4, lines 38-39, refers to a flexion and extension of the joint after the bone and rods are resorbed. However, this appears to directly contradict what is actually stated by Cohen. Rather, Cohen states “After placement, the stability and position of the toe is checked. Flexion and extension of the joint should not result in dislocation of the implant.” Clearly, the implant is still present when flexion and extension are tested. It has not been resorbed as Applicant argues.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 305-3580.

Application/Control Number: 09/289,000

Page 9

Art Unit: 3738

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.



Paul Prebilic
Primary Examiner
Art Unit 3738